

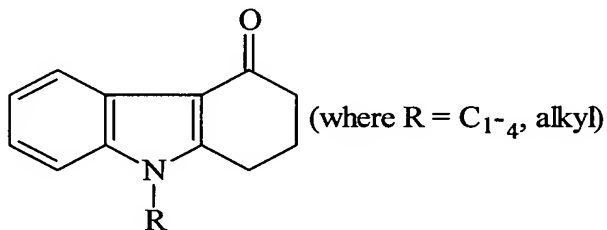
Amendments to the Claims:

Please amend claims 42-47 as follows.

Please add new claims 48 and 49.

Please cancel claims 4-41 without prejudice.

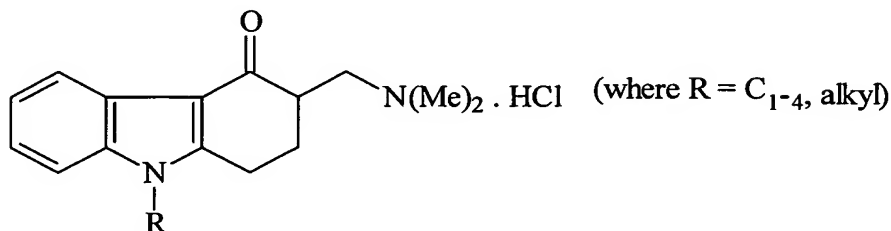
- Claim 1 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0%.
- Claim 2 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5%.
- Claim 3 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9%.
- Claim 4 (cancel) A process for preparing dimethylamino-methyl-carbazolone comprising the steps of:
- a) preparing a solution of methyl-carbazolone having the formula:



- b) heating the solution in the presence of dimethylamine hydrochloride and paraformaldehyde;
- c) basifying the solution to form a precipitate;
- d) separating the precipitate from the solution;
- e) drying the precipitate.
- Claim 5 (cancel) The process according to claim 4, wherein R is methyl.
- Claim 6 (cancel) The process according to claim 4, wherein the heating step is performed at a temperature of about 70⁰C to about 100⁰C.
- Claim 7 (cancel) The process according to claim 4, wherein the heating step is performed at a temperature of about 80⁰C to about 90⁰C.
- Claim 8 (cancel) The process according to claim 4, wherein the heating step is

- performed for about 6 to about 24 hours.
- Claim 9 (cancel) The process according to claim 4, wherein the heating step is performed for about 6 to about 12 hours.
- Claim 10 (cancel) The process according to claim 4, wherein the heating step is performed in acetic acid.
- Claim 11 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and paraformaldehyde.
- Claim 12 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 13 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 14 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 15 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 to about 6 volumes of acetic acid.
- Claim 16 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 volumes of acetic acid.
- Claim 17 (cancel) The process according to claim 4, wherein the solution of methyl-carbazolone is basified by about 45% sodium hydroxide.
- Claim 18 (cancel) The process according to claim 17, wherein the solution is basified to a pH of about 13 to about 14.
- Claim 19 (cancel) The process according to claim 17 or 18, wherein the basifying step is performed in the presence of 10% celite.
- Claim 20 (cancel) A process for preparing ondansetron base, comprising the steps of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



b) heating the solution;
c) removing a precipitate containing ondasetron base from the solution;
d) washing the precipitate;
e) drying precipitate to obtain ondansetron base.

Claim 21 (cancel) The process according to claim 20, wherein the solution is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 22 (cancel) The process according to claim 20, wherein the solution is prepared by adding about 5 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 23 (cancel) The process according to claim 20, wherein the solution is prepared in the presence of 10% celite.

Claim 24 (cancel) The process according to claim 20, further comprising the step of: recrystallizing ondansetron base.

Claim 25 (cancel) The process according to claim 24, wherein the recrystallizing step is performed in the presence of activated carbon and methanol.

Claim 26 (cancel) A process of preparing pure ondansetron hydrochloride dihydrate comprising the steps of:
a) preparing a solution of ondansetron base;
b) acidifying the solution with hydrogen chloride to form a precipitate;

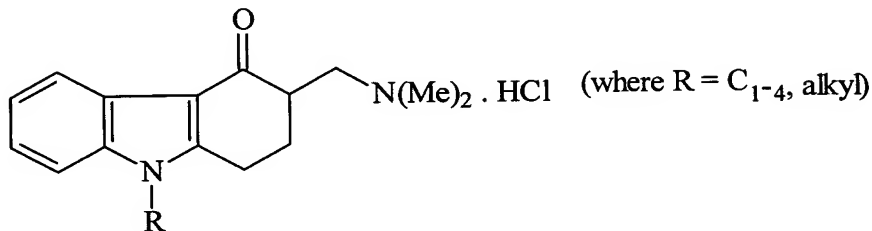
- c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate.
- Claim 27 (cancel) The process according to claim 26 wherein about 3 to about 7 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.
- Claim 28 (cancel) The process according to claim 26 wherein about 5 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.
- Claim 29 (cancel) The process according to claim 26 wherein about 1.0 to about 1.4 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.
- Claim 30 (cancel) The process according to claim 26 wherein about 1.1 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.
- Claim 31 (cancel) The process of claims 29 or 30, wherein the solution is acidified to a pH about 1 to about 4.
- Claim 32 (cancel) The process of claims 29 or 30, wherein the solution is acidified to a pH about 3.
- Claim 33 (cancel) The process according to claim 26, wherein the precipitate is washed with about 5 to about 15 ml of isopropanol.
- Claim 34 (cancel) The process according to claim 26, wherein the precipitate is washed with about 10 ml of isopropanol.
- Claim 35 (cancel) The process according to claim 26, wherein the crystallizing step is achieved by adding about 3 to about 5 volumes of water to induce crystallization.
- Claim 36 (cancel) The process according to claim 26, wherein the crystallizing step is achieved by adding about 4 volumes of water to induce crystallization.
- Claim 37 (cancel) The process according to claim 26, wherein the crystallization step is repeated two times.
- Claim 38 (cancel) The process according to claim 26, wherein the crystallizing step is achieved in the presence of activated carbon.
- Claim 39 (cancel) The process according to claim 36, wherein the activated

carbon is selected from the group consisting of SX-2, CA-1, CXV and SX-1.

- Claim 40 (cancel) The process according to claim 39, wherein the activated carbon is about 5 to about 15% SX-1.
- Claim 41 (cancel) The process according to claim 39, wherein the activated carbon is about 5 to about 10% SX-1.
- Claim 42 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has~~ having a purity of at least about 99.0% prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- Claim 43 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate have~~ having a purity of at least about 99.5% prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- Claim 44 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has~~ having a purity of at least about 99.9% prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

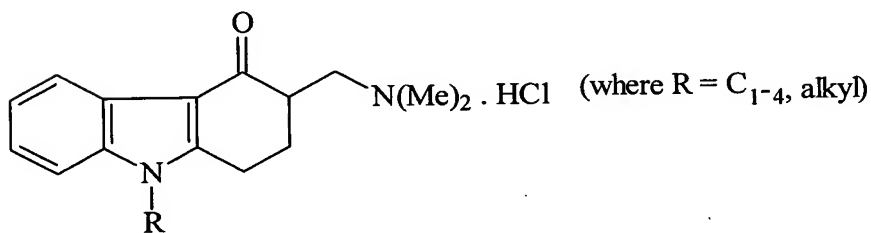
- Claim 45 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- Claim 46 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- Claim 47 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
- a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
 - d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- Claim 48 (new) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the ondansetron base is prepared by the process of:

- a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



- b) heating the solution;
c) removing a precipitate containing ondansetron base from the solution;
d) washing the precipitate;
e) drying precipitate to obtain ondansetron base;
wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 49 (new) The pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as in claim 45, 46, or 47, wherein the ondansetron base is prepared by the process of:
a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



- b) heating the solution;
 - c) removing a precipitate containing ondansetron base from the solution;
 - d) washing the precipitate;
 - e) drying precipitate to obtain ondansetron base;
- wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.